AUG 15 2003

K032372

Nucletron

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	Comfort Catheter System
Common/Usual Name:	Remote Afterloading for interstitial Brachytherapy applications
Classification Name:	Remote controlled radionucide applicator system accessory
Classification:	21Cfr892.5700 Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Implant Guidance System	K020015

Description:

The Nucletron Comfort Catheter System as described in this submission is designed as an accessory to the Nucletron remote afterloading equipment. mHDR and is intended for interstitial Brachytherapy procedures.

The device consists of a Leader insertion needle with an obturator which is inserted through the skin surface into the target volume, i.e. breast. The obturator is then removed and the

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flexible implant tube is inserted into hollow needle, the hollow needle is retracted when the flexible implant tube is in place. Optional a template can be used for positioning the insertion needles.

Once the catheter is in place the insertion needle is removed and a button is placed over the plastic catheter and slid into contact with the skin surface. .The Flexible implant tube is pulled in.position until the distal button is in contact with the skin surface. The proximal button is pulled over the flexible implant tube, until the button is in contact with the skin surface. The flexible implant tubes are cut off, at a predetermined length with the cutter. A flange is molded on the flexible implant tube with the flange molding tool, to fixate the proximal button.

X-ray catheters or CT markers are inserted into the Proguide treatment needles for visualisation. Radiographic images, planar films or transverse slices, i.e. CT, MR is obtained to determine the precise location of the applicator within the body. This information is then used for Brachytherapy treatment planning purposes.

The Proguide treatment needles are a closed system to prevent the radioactive source from coming in contact with body fluids. The treatment catheter does not control the treatment unit; it strictly provides a treatment path for the radioactive source. The afterloader and the clinical staff verify that the applicator is properly attached prior to treatment.

For the first treatment a closed end Proguide treatment needle is inserted up to the distal end of the flexible implant tube. The Proguide treatment needle is immobilised with a stoptag. The Proguide treatment needle is attached to the afterloader (treatment head), using transfer tubes. When the applicator is attached, a check cable run is performed to ensure that the applicator is properly attached and that there are no obstructions, which will interrupt treatment. After the check cable run, the radioactive source will step through the applicator to deliver the prescribed dose of radiation.

After the treatment the Proguide treatment needles are disconnected from the attached transfer tubes and from the implant (flexible implant tubes) by using the stop tags. In between treatment fractions the Proguide treatment needle are stored in a patient treatment box. The Stop tags must remain fixed on the Proguide treatment needles for the next fraction. When the course of treatment is completed the flexible implant tubes and buttons are removed from the patient.

The device uses similar (implantable) materials as the legally marketed predicate device cited (Implant Guidance System). With respect to the legally marketed predicate device cited (MicroSelectron HDR V2: Breast Template), the implant technique has been optimised for interstitial techniques such as breast implants, no longer the catheters are protruding from the patients body in between fractions. This increases the patient comfort and flexibility. It is also easier for the hospital staff to apply and remove the catheters.

The Comfort Catheter System is used as an accessory to the Nucletron microSelectron.

Intended use:

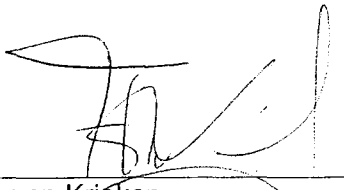
The modified device has the same intended use as the legally marketed predicate device cited:

Comfort Catheter System is intended for interstitial Brachytherapy procedures involving the Nucletron remote afterloading equipment: mHDR.

Summary of technological considerations:

K032392

The Comfort Catheter System is substantially equivalent to the cleared predicate device, Comfort Catheter System, 510(k)#: K020015.



13-06-2003

Name: Frits van Krieken
Title: Business Segment Manager
Nucletron B.V.
Veenendaal, The Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2003

Nucletron B.V.
% Mr. Peter N. Ruys
Responsible Third Party Official
KEMA Quality B.V.
Utrechtseweg 310
NL-6812 AR Arnhem
THE NETHERLANDS

Re: K032372
Trade/Device Name: Comfort Catheter System
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: July 31, 2003
Received: August 1, 2003

Dear Mr. Ruys:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number	K032372
Device Name	Comfort Catheter System
Indications for Use	Comfort Catheter System is intended for interstitial Brachytherapy procedures involving the Nucletron remote afterloading equipment: mHDR.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032372